In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

DUANE HOFFMAN,	*	
	*	No. 19-111V
Petitioner,	*	Special Master Christian J. Moran
	*	
v.	*	
	*	Filed: January 10, 2024
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Isaiah Kalinowski, Bosson Legal Group, P.C., Fairfax, VA, for petitioner;
Felicia D. Langel, United States Dep't of Justice, Washington, DC, for respondent.

DECISION DENYING COMPENSATION[1]

Duane Hoffman alleges that an influenza ("flu") vaccine caused him to develop a neurologic problem, chronic inflammatory demyelinating polyneuropathy ("CIDP"). Mr. Hoffman supported his claim with reports from a neurologist retained for this litigation, Zurab Nadareishvili. The Secretary disputes Mr. Hoffman's claim that the flu vaccine injured him and has, likewise, supported his position with reports from a neurologist the Secretary retained for this

[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

litigation, Michael Wilson. Following the submission of these reports, the parties advocated through memoranda.

For the reasons explained below, Mr. Hoffman is not entitled to compensation. Mr. Hoffman has based part of his claim on a level of proof (plausibility) that is lower than the required level of proof, which is preponderant evidence. Under the correct burden of proof, Mr. Hoffman has failed to show how a flu vaccine can cause CIDP. Thus, he is not entitled to compensation.

I. Background[2]

Mr. Hoffman was born in 1960. For many years, he worked as a corrections officer, although he was not employed when he received the allegedly causal flu vaccination in 2017. Exhibit 23 (affidavit regarding damages).

More than two years before the flu vaccination, Mr. Hoffman was diagnosed with chronic lymphocytic leukemia ("CLL"). Exhibit 10 at 7 (Mar. 31. 2015). The Secretary's expert, Dr. Wilson, has proposed that the leukemia is associated with an increased risk for CIDP. Exhibit A at 5.

In January 2017, Mr. Hoffman was hospitalized due to an exacerbation of chronic obstructive pulmonary disease. Exhibit 4 at 657. While hospitalized, Mr. Hoffman received the flu vaccine. Exhibit 1. (Mr. Hoffman also received a pneumococcal vaccine but his claim rests upon the flu vaccine.)

Mr. Hoffman was diagnosed with low back pain on January 24, 2017. Exhibit 4 at 819, 862. This pain continued and Mr. Hoffman developed other problems for which he was admitted to Riverside Methodist Hospital. In Riverside Methodist Hospital, Mr. Hoffman underwent tests, including an EMG/NCS. Based upon the results, Mr. Hoffman's doctors diagnosed him with a neurologic disorder, Guillain-Barré syndrome. Exhibit 7 at 261, 876-81.

---

[2] Events in Mr. Hoffman's life are presented summarily because this case is being resolved on an element of proof, the causal theory allegedly connecting flu vaccines to CIDP, that is largely independent of what happened to Mr. Hoffman. In addition, the parties agree that the medical records accurately describe what happened to Mr. Hoffman close in time to when the medical record was created. Thus, there are no disputes about what transpired in Mr. Hoffman's case. For more detailed accounts of the medical records, see Am. Pet., filed Sep. 17, 2020, at 1-6; Resp't's Resp., filed Sep. 21, 2022, at 2-5.

Guillain-Barré syndrome is:

(i) … an acute monophasic peripheral neuropathy that encompasses a spectrum of four clinicopathological subtypes described below. For each subtype of GBS, the interval between the first appearance of symptoms and the nadir of weakness is between 12 hours and 28 days. This is followed in all subtypes by a clinical plateau with stabilization at the nadir of symptoms, or subsequent improvement without significant relapse. Death may occur without a clinical plateau. Treatment related fluctuations in all subtypes of GBS can occur within 9 weeks of GBS symptom onset and recurrence of symptoms after this time-frame would not be consistent with GBS.

(ii) The most common subtype in North America and Europe, comprising more than 90 percent of cases, is acute inflammatory demyelinating polyneuropathy (AIDP), which has the pathologic and electrodiagnostic features of focal demyelination of motor and sensory peripheral nerves and nerve roots. . . . AIDP [is] typically characterized by symmetric motor flaccid weakness, sensory abnormalities, and/or autonomic dysfunction caused by autoimmune damage to peripheral nerves and nerve roots. The diagnosis of AIDP. . . requires:

> (A) Bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs;
>
> (B) A monophasic illness pattern;
>
> (C) An interval between onset and nadir of weakness between 12 hours and 28 days;
>
> (D) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau); and,
>
> (E) The absence of an identified more likely alternative diagnosis.

* * *

(v) To qualify as any subtype of GBS, there must not be a more likely alternative diagnosis for the weakness.

> (vi) Exclusionary criteria for the diagnosis of all subtypes of GBS include the ultimate diagnosis of any of the following conditions: chronic immune demyelinating polyradiculopathy (CIDP) . . .

42 C.F.R. § 100.3(c)(15).

Mr. Hoffman's doctors prescribed a standard treatment for GBS, the infusion of intravenous immunoglobulin ("IVIG"). In early 2017, when Mr. Hoffman's doctors were treating him for GBS, at least one doctor stated that the flu vaccine caused Mr. Hoffman's GBS. Exhibit 7 at 266; see also Exhibit 4 at 1053 (note, from an unknown source, that Mr. Hoffman's allergies include the flu vaccine).

Mr. Hoffman attempted rehabilitation for several months and sought care from various doctors. One neurologist, Geoffrey Eubank, ordered a test for anti-ganglioside antibodies. The results were negative. Exhibit 9 at 32.

Approximately eight months after the diagnosis of GBS, Mr. Hoffman saw Dr. Eubank again. Exhibit 19 at 66 (Oct. 9, 2017). Dr. Eubank changed the diagnosis to CIDP. He explained his rationale. Dr. Eubank

> previously thought that [Mr. Hoffman] had Guillain Barre syndrome but . . . [h]e continued to have some worsening this summer and subsequently improved with a course of IVIG for 5 days. This would not be typical for Guillain Barre which should be more of a monophasic illness.

Id.

Another neurologist, Timothy Rust, confirmed the diagnosis of CIDP. Exhibit 19 at 58 (Dec. 13, 2017). Dr. Rust wrote that "CLL can be associated with peripheral nervous system pathology similar to non-Hodgkin lymphoma, including a relatively high rate of CIDP." Id.

The diagnosis of CIDP is accepted by the neurologists retained to provide opinions. Exhibit 30 at 7; Exhibit A at 3-4.[3] "CIDP" stands for "chronic

[3] In the Vaccine Program, petitioners often allege that a vaccine caused them to suffer CIDP. Thus, special masters are generally familiar with CIDP. For some examples of recent

inflammatory demyelinating polyneuropathy," which explains the basic information about the disease. See Exhibit A at 4. Although most cases of CIDP develop insidiously, CIDP can develop abruptly as in Mr. Hoffman's case. Exhibit 30 at 7, Exhibit A at 4.

As discussed below, the etiology of CIDP is "poorly understood." Exhibit A at 5. According to Dr. Nadareishvili, "An abundance of clinical and experimental research has led to the conclusion that CIDP is mediated by humoral and cellular immunity against Schwann cell/myelin target antigens in the nerves, thus its classification as an autoimmune disease." Exhibit 30 at 9. A primary question in this litigation is whether the flu vaccine can provoke an autoimmune attack, which leads to CIDP.

II. Procedural History

Initially, Mr. Hoffman alleged that the flu vaccine caused him to suffer GBS. Pet., filed Jan. 22, 2019, ¶ 15. He sought compensation via the Vaccine Injury Table and adjudication through the special processing unit of the Office of Special Masters. Id. ¶ 20-21. The case was assigned to the special processing unit. Mr. Hoffman periodically filed medical records.

The Secretary reviewed the evidence and recommended that compensation be denied. Resp't's Rep., filed June 12, 2020. The Secretary maintained that based upon the records from Dr. Eubank and Dr. Rust, Mr. Hoffman suffered from CIDP, not GBS. Id. at 8. Because resolution through the special processing unit seemed infeasible, the case was reassigned. Notice, issued June 25, 2020.

Mr. Hoffman changed his claim. He alleged that the flu vaccine was the cause-in-fact of his CIDP. Am. Pet., filed Sep. 17, 2020.

Mr. Hoffman supported his claim that the flu vaccine caused his CIDP with a report from Dr. Nadareishvili. Exhibit 30. Dr. Nadareishvili stated that CIDP is

---

opinions about CIDP, see Radford v. Sec'y of Health & Hum. Servs., No. 18-704V, 2023 WL 2159306, at *7-12 (Fed. Cl. Spec. Mstr. Feb. 22, 2023); Berg v. Sec'y of Health & Hum. Servs., No. 16-650V, 2021 WL 6883495 at *24-37 (Fed. Cl. Spec. Mstr. Dec. 14, 2021); Tomsky v. Sec'y of Health & Hum. Servs., No. 17-1132V, 2020 WL 5587365, at *8-18 (Fed. Cl. Spec. Mstr. Aug. 24, 2020).

similar to GBS. He proposed that the flu vaccine can cause CIDP via molecular mimicry. Id. at 7-16.

The Secretary countered by presenting a report from a neurologist, Michael Wilson. Exhibit A. Dr. Wilson disputed molecular mimicry as a theory to explain how a flu vaccine might cause CIDP. Id. at 4-5. Dr. Wilson noted that to the extent that molecular mimicry might predict an attack on gangliosides as causing CIDP, this theory would not explain what happened to Mr. Hoffman because a test for anti-ganglioside antibodies was negative. Id. at 5. Finally, Dr. Wilson suggested that chronic lymphocytic leukemia is associated with CIDP. Id. at 5.

Dr. Nadareishvili responded to Dr. Wilson in a report filed on January 11, 2022. Exhibit 63. Dr. Nadareishvili contended that Dr. Wilson did not explain how CLL can cause CIDP. Id. at 3.

Dr. Wilson replied that he did not say that CLL can cause CIDP because "No one knows what triggers CIDP." Exhibit C at 2 (filed Mar. 14, 2022). In an ensuing status conference, the Secretary was asked how Mr. Hoffman's chronic lymphocytic leukemia affects the case given that Dr. Wilson has not presented any mechanism by which CLL can cause CIDP. The Secretary stated that he might obtain a report from a different expert and Mr. Hoffman objected to adding a new expert on the ground that Mr. Hoffman's CLL had been in the record. The Secretary eventually reported that he was not interested in settlement and will continue to defend the case. Resp't's Status Rep., filed Apr. 27, 2022.

The parties were directed to file briefs. Order, issued July 18, 2022. Mr. Hoffman filed his primary brief on August 22, 2022 and his reply on October 5, 2022. In between, the Secretary filed his brief on September 21, 2022.

With the submission of the reply, Mr. Hoffman's case is ready for adjudication. Mr. Hoffman requested a ruling that he was he entitled to compensation based upon the record. He did not seek a hearing. See Pet'r's Br. at 2, 4. The Secretary also did not request a hearing. See Resp't's Br. Because both parties have had a fair opportunity to present their evidence and their arguments, an adjudication based upon the papers is appropriate. See Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2018).

III. Standards for Adjudication

A petitioner is required to establish his case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

When a petitioner, like Mr. Hoffman, claims that a vaccine caused an injury not listed on the Vaccine Injury Table, such as CIDP, the elements of a petitioner's case are well defined. A petitioner bears a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Mr. Hoffman's case is being resolved upon prong one exclusively. Thus, an examination of the remaining prongs is not required.

IV. Analysis

Two steps are required to evaluate Mr. Hoffman's assertion that a flu vaccine can cause CIDP. The first is to determine the level of proof on this element. The second is to assess whether the evidence satisfies the standard. An additional aspect is to compare the outcome in Mr. Hoffman's case with the

outcome in other cases evaluating the Althen's first prong in the context of a flu vaccine allegedly causing CIDP.

A. Burden of Proof for *Althen* Prong One

Mr. Hoffman recognizes that his burden of proof is preponderant evidence. Pet'r's Br. at 8, quoting 42 U.S.C. § 300aa–13(a)(1)(A). But, Mr. Hoffman argues that a medical theory proposing a causal connection between a vaccine and an injury needs to be only plausible. Id. at 17-18 (citing cases); Pet'r's Reply at 4-11. Consistent with this position, Mr. Hoffman contends that the theory Dr. Nadareishvili proposes is plausible. E.g. Pet'r's Br. at 23-24.

On the other hand, the Secretary argues that any medical theory must be persuasive and reliable. Resp't's Br. at 7-8. The Secretary, therefore, criticizes Mr. Hoffman for using the wrong standard. Id. at 12.

Plausibility requires a lower degree of evidence than probability. Cerrone v. Sec'y of Health & Hum. Servs., No. 17-1158V, 2023 WL 9185794 (Fed. Cl. Nov. 6, 2023), appeal docketed, No. 24-1281 (Fed. Cir. Dec. 22, 2023); Jane Doe 93 v. Sec'y of Health & Hum. Servs., No. Redacted, 2011 WL 2326966, at *1 (Fed. Cl. Spec. Mstr. May 9, 2011). An evidentiary scale might include markers for "what is possible," "what is plausible," "what is persuasive," "what is convincing," and "what is certain."

Repeatedly, Mr. Hoffman juxtaposes "plausible" with "certainty." He argues: "The lack of a proven pathway is an issue for those concerned with scientific certainty; biologic plausibility has clearly been achieved, at least for the foremost experts on the condition." Pet'r's Br. at 26. For other examples, see Pet'r's Br. at 32, 40. This contrast, however, is misleading. The correct burden of proof is neither plausibility nor certainty. The correct burden of proof is preponderant evidence, sometimes referred to as "probability" or "probable."

An extensive analysis of this issue is not required in this decision because within the last two calendar years, judicial officers have already held that the burden of proof for Althen prong one is persuasive evidence. Two opinions from the Court of Federal Claims stand out for their reasoning: Trollinger v. Sec'y of Health & Hum. Servs., 167 Fed. Cl. 127, 137 (2023), and Howard v. Sec'y of Health & Hum. Servs., No. 16-1592V, 2023 WL 4117370, at *4-5 (Fed. Cl. May 18, 2023) (discussing cases decided before Moberly), appeal docketed, No. 2023-

1816 (Fed. Cir. Apr. 28, 2023).[4] Special masters have reached the same conclusion. Singleton v. Sec'y of Health & Hum. Servs., No. 17-1474V, 2023 WL 3595653, at *20 (Fed. Cl. Spec. Mstr. May 23, 2023); J.D. v. Sec'y of Health & Hum. Servs., No. 14-742V, 2022 WL 16543853, at *27 (Fed. Cl. Spec. Mstr. Aug. 31, 2022).

The reasoning in those opinions is persuasive. The undersigned also holds that a petitioner's burden regarding Althen prong one is to present persuasive evidence.

A holding that Mr. Hoffman must present a persuasive theory, by itself, may justify a finding that Mr. Hoffman did not meet his burden of proof. As noted above, Mr. Hoffman consistently contended that his proof of a medical theory was plausible. Proof at merely a plausible level is insufficient as a matter of law as illustrated in Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351 (Fed. Cir. 2019). There, the petitioners' expert presented a theory that was "only 'plausible.'" Id. at 1360, quoting the special master's decision. The Federal Circuit held that the "Special Master erred in allowing a theory that was at best 'plausible' to satisfy the Petitioners' burden of proof." Id.

Given the outcome in Boatmon, which was a Federal Circuit's affirmance of a judgment denying compensation, it appears that a similar outcome should be reached here, a decision denying compensation. However, it is conceivable that the evidence surpasses the correct threshold even if Mr. Hoffman, himself, did not categorize his case that way. For this reason and to demonstrate that all evidence relevant to Althen prong one has been considered, the undersigned will next evaluate Mr. Hoffman's proposed theory.

B. Molecular Mimicry as a Theory

Through Dr. Nadareishvili, Mr. Hoffman advances molecular mimicry as a biologically plausible way that a flu vaccine can cause CIDP. Pet'r's Br. at 24-40;

[4] These opinions from the Court of Federal Claims are not binding precedent. However, they remain a type of precedent from an appellate tribunal capable of persuading by their reasoning.

see also Exhibit 30 at 11.[5] Multiple appellate cases have provided guidance on how special masters should assess molecular mimicry. These non-binding precedents are discussed as a preliminary matter. After this foundation, the evidence is further evaluated.

1. Appellate Cases regarding Molecular Mimicry

Because special masters are often called upon to evaluate the persuasiveness of the theory of molecular mimicry, the Court of Federal Claims and the Court of Appeals for the Federal Circuit have considered molecular mimicry in their appellate role of reviewing opinions.[6] In December 2019, the undersigned identified the leading precedents as W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352 (Fed. Cir. 2013), and Caves v. Sec'y of Dep't. of Health & Hum. Servs., 100 Fed. Cl. 119 (2011), aff'd sub nom., 463 F. App'x 932 (Fed. Cir. 2012). Tullio v. Sec'y of Health & Hum. Servs., No. 15-51V, 2019 WL 7580149, at *12-14 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448 (2020). While Tullio describes those cases in more detail, their essence appears to be that although molecular mimicry is accepted in some contexts, special masters may properly require some empirical evidence to show that a particular vaccine can cause a particular disease.

In the next approximately three years, appellate authorities reviewing decisions involving molecular mimicry have generally endorsed the approach of looking for some evidence that persuasively shows that a portion of a vaccine resembles a portion of human tissue, which contributes to causing the disease, and that the immune system will respond to the relevant amino acid sequence.[7] Chronologically, the list of more recent appellate cases begins with the opinion in Tullio, which denied the motion for review. 149 Fed. Cl. 448, 467-68 (2020).

---

[5] Although Mr. Hoffman alludes to "other pathologic mechanisms," Pet.'r's Br. at 24, he has not developed any argument with regard to pathologic mechanisms except for molecular mimicry.

[6] The briefs would have been improved if they had discussed any appellate cases about molecular mimicry.

[7] The term "homology" is used when discussing molecular mimicry. "Homology" is defined as "the quality of being homologous; the morphological identity of corresponding parts; structural similarity due to descent from a common form." *Dorland's* at 868.

Another example in which the Court of Federal Claims held that the special master did not elevate the petitioner's burden of proof in the context of evaluating the theory of molecular mimicry is Morgan v. Sec'y of Health & Hum. Servs., 148 Fed. Cl. 454, 476-77 (2020), aff'd in non-precedential opinion, 850 F. App'x 775 (Fed. Cir. 2021). In Morgan, the Chief Special Master found that petitioner had not presented persuasive evidence about a relevant antibody. Id. at 477. The Chief Special Master also noted that the articles about the relevant disease do not list the wild flu virus as potentially causing the disease. Id. When examining this analysis, the Court of Federal Claims concluded: "the Chief Special Master did not raise the burden of causation in this case; petitioner simply failed to meet it." Id.

The Federal Circuit also evaluated the Chief Special Master's approach in Morgan. The Federal Circuit concluded: "We discern no error in the special master's causation analysis." 850 F. App'x 775, 784 (Fed. Cir. 2021).

Most other recent appellate cases follow this path. See, e.g., Duncan v. Sec'y of Health & Hum. Servs., 153 Fed. Cl. 642, 661 (2021) (finding the special master did not err in rejecting a bare assertion of molecular mimicry); Caredio v. Sec'y of Health & Hum. Servs., No. 17-79V, 2021 WL 6058835, at *11 (Fed. Cl. Dec. 3, 2021) (indicating that a special master did not err in requiring more than homology and citing Tullio); Yalacki v. Sec'y of Health & Hum. Servs., 146 Fed. Cl. 80, 91-92 (2019) (ruling that special master did not err in looking for reliable evidence to support molecular mimicry as a theory); but see Patton v. Sec'y of Health & Hum. Servs., 157 Fed. Cl. 159, 169 (2021) (finding that a special master erred in requiring petitioner submit a study to establish medical theory causally connecting flu vaccine to brachial neuritis).

Very recently, the Court of Federal Claims explained why petitioners must present some evidence to show the persuasiveness of molecular mimicry as a theory in their cases. Dennington v. Sec'y of Health & Hum. Servs., 167 Fed. Cl. 640 (2023), appeal docketed, No. 2024-1214 (Fed. Cir. Dec. 1, 2023). There, Ms. Dennington alleged that a tetanus-diphtheria-acellular pertussis ("Tdap") vaccine caused her to develop GBS. Id. at 644. She supported her claim with two reports from a neurologist, Carlo Tornatore, who put forward molecular mimicry. Id. at 647-49. The chief special master denied entitlement. Id. at 656.

In an opinion made available to the public on October 6, 2023, the Court of Federal Claims denied a motion for review because the chief special master did not commit any error in evaluating Ms. Dennington's prong one evidence. The Court emphasized the lack of evidence supporting Dr. Tornatore's opinion:

- "While Petitioner and Dr. Tornatore put forth the well-established medical theory of molecular mimicry as the mechanism through which the Tdap vaccine could cause GBS, nowhere in Dr. Tornatore's expert reports, nor in Petitioner's briefs, do they specifically tie the Tdap vaccine to GBS through molecular mimicry." Id. at 653.

- "Dr. Tornatore never actually explains how molecular mimicry might occur from the Tdap vaccine specifically, nor does he elaborate on how molecular mimicry could cause the specific autoimmune system reaction that could cause GBS." Id.

- "There is nothing in Dr. Tornatore's report that explains or even alludes to what antigens or structures in the Tdap vaccine could share homology with possible host antigens and how these antigens could react in the manner GBS is believed to progress." Id. at 654.

- "The literature upon which he relies make no mention of any causal connection between GBS and the Tdap vaccine." Id.

Based upon these observations, the Court criticized the lack of specificity in Dr. Tornatore's opinions:

> In fact, because Dr. Tornatore does not offer any specific explanation as to the distinct connection between Tdap, molecular mimicry, and GBS, one could take Dr. Tornatore's causation theory and substitute any table vaccine (e.g., the measles vaccine) and any autoimmune disorder (e.g., autoimmune encephalitis) and Dr. Tornatore's expert report's discussion of molecular mimicry would require absolutely no changes. That is how general his molecular mimicry theory is—it does not matter which vaccine and which autoimmune disorder are plugged in. But *Althen* prong one requires more.

Id.

In accordance with precedents such as W.C., Caves, Tulio, Yalacki, and Dennison, the undersigned will look to see whether any evidence supports the theory that flu vaccine can cause CIDP.

2. Evidence regarding Molecular Mimicry

Evidence regarding whether molecular mimicry is a persuasive theory to explain how a flu vaccine could cause CIDP falls into two broad, and somewhat overlapping, categories. The first is evidence about flu vaccines (or flu infections) and CIDP. The second is evidence about flu vaccine (or flu infections) and GBS.

"A petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be legally probable, not medically or scientifically certain." Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1345 (Fed. Cir. 2010) (internal quotation marks and citation omitted). Due to the requirement that the explanation "pertains specifically to the petitioner's case," the analysis starts with the evidence that directly concerns the condition for which Mr. Hoffman seeks compensation, CIDP.

a) Flu Infections, Flu Vaccines, and CIDP

CIDP is considered an "immune-mediated neuropathy." Exhibit 30 at 9. This means that a person's immune system attacks components of the nervous system. A similar term is "autoimmune." See Exhibit 32 at 768 (Lunn and Sheikh).[8]

Beyond the point that CIDP is autoimmune in origin, relatively little is understood about CIDP. An article published in 2015 states: "Although CIDP is classed as an autoimmune disorder in which an aberrant immune response is directed towards components of the peripheral nerve causing demyelination and axonal damage, the exact mechanisms underlying the development of immunopathology remain to be defined." Exhibit 50 at 1 (Mathey).[9] A similar point is made in another 2015 article: "no specific antibody has yet been identified

[8] "Exhibit 31" is shown on the actual medical article; however, the comprehensive exhibit list, submitted on April 1, 2023, indicates that this article is "Exhibit 32." "Exhibit 31" is shown on Dr. Nadareishvili's curriculum vitae as well. The comprehensive exhibit list indicates that Dr. Nadareishvili's curriculum vitae is "Exhibit 31." It appears that the Exhibit number on the medical article is inaccurate. This decision will cite to this medical article as Exhibit 32.

[9] Petitioner submitted this article in manuscript form. Therefore, the page cites are to the pdf version, rather than the version that appears in printed journals.

as the causative factor in CIDP, in spite of the compelling indirect evidence." Exhibit 62 at 662 (Dalakas).

Consistent with these articles that he cited, Dr. Nadareishvili wrote "the precise pathogenesis" of CIDP is "not well fully [sic] delineated. No expert in the fields of neurology or immunology would claim to understand exactly how a particular immune trigger leads inexorably to CIDP." Exhibit 30 at 12.

This lack of understanding does not prevent Dr. Nadareishvili from proposing that the flu vaccine can cause CIDP via molecular mimicry. Molecular mimicry, as noted in multiple judicial opinions, is frequently proposed by doctors supporting claims that a vaccine injured someone. See, e.g., Dennington, 2023 WL 6529518. Dr. Nadareishvili cited a 2006 article co-written by one of the originators of the theory of molecular mimicry, Robert S. Fujinami. Exhibit 35 (Fujinami).

References postulating molecular mimicry as contributing to CIDP appear scant in Mr. Hoffman's case. (There are, however, multiple references about molecular mimicry and GBS, which are discussed below.) For CIDP specifically, one article from more than two decades ago suggested the body's response to a malignant melanoma might lead to CIDP through molecular mimicry. Exhibit 41 (Weiss). Another article discusses molecular mimicry between melanoma cells and myelin. Exhibit 62 at 662 (Dalakas). The originating Weiss article, in turn, was cited in a chapter about CIDP in a leading neurology text book. Exhibit 51 at 2228, 2245 (Hahn). (Weiss is reference 231 in the chapter by Hahn). These authors raised molecular mimicry as a "potentially relevant mechanism in the pathogenesis of CIDP." Id. at 2245. They continued: "Although CIDP is rarely associated with carcinomas, the connection with melanoma is of great interest because both melanoma and Schwann cells derive from neural crest tissues and share common antigens." Id.

Although not in the context of molecular mimicry, the authors of this textbook chapter discussed the potential link between infections or vaccinations and CIDP. They wrote: "Whereas AIDP [acute inflammatory demyelinating polyneuropathy, which is a type of GBS] can often be linked to a preceding viral or bacterial infection, this association is much less apparent in CIDP." Exhibit 51 at 2223. The lack of association might be because of "the common delay in making the diagnosis (on average 6 to 12 months from onset of symptoms)," such that "patients may simply no longer recall such prodromal events." Id. These authors

reviewed four studies, of which one (McCombe) was submitted as an exhibit here. Hahn and colleagues interpreted the data:

> The observation that onset or relapse of CIDP was linked to infections or immunization in 19% to 32% of reported cases suggests that the association is higher than expected by chance alone. However, none of the reported studies had examined in parallel the incidence of infections in control populations. Therefore, a direct or indirect relationship between CIDP and the preceding events remains to be established.

Id. at 2224.

In an article published in 1987, McCombe and colleagues reported information about 92 cases of CIDP. Of this group, 29 people (or 32 percent) gave a history of an event in the preceding six weeks. Exhibit 55 at 1622 (McCoumbe). Of the 29 people, four reported receiving a vaccine--- 1 reported a smallpox vaccination, 2 reported the Salk polio vaccination, and 1 reported a tetanus vaccination. Id. As the Secretary pointed out, no one reported receiving the flu vaccination. Resp't's Br. at 14 n.11.

Another survey of 100 people with CIDP was reported in 1990 by Bouchard and colleagues. Exhibit 56 (Bouchard). Of this group, 16 patients "noted an infectious event within 6 weeks before the initial neurologic manifestations." Id. at 499. Again, Bouchard did not report any instances of any vaccination preceding the onset of CIDP. See Resp't's Br. at 14 n.11.

A third article discussing a potential connection between infections and/or immunizations and CIDP is Kuitwaard. Exhibit 60. This article potentially carried great weight in supporting the theory that a flu vaccine can cause CIDP because Mr. Hoffman maintained this article presented "evidence of a rechallenge response, which is a strong measure of biologic plausibility." Pet'r's Br. at 36. However, this description oversells the data Kuitwaard contains.

Kuitwaard and others reported the results of a survey that they sent to members of the Dutch society of neuromuscular disorders. Exhibit 60 at 310 (Kuitwaard). The researchers received responses from 76 CIDP patients. The patients completed the questionnaire on average approximately six years after the onset of their CIDP (range 0-29 years). Id. at 312. Eight CIDP patients (about 11

percent) reported receiving a vaccination within the preceding 8 weeks. Id. "Of the 24 patients who received a flu vaccination (range 1–17 times) after being diagnosed with CIDP, five reported an increase in symptoms after one or more vaccinations." Id.

The authors recognized some methodological limitations. Among them was the possibility of "recall bias" due to the "retrospective nature of part of the questionnaires." Id. at 315. The authors explained: "It is difficult to draw firm conclusions from a questionnaire in which patients report their recurrences after vaccinations themselves." Id. The authors did not suggest any warnings about vaccinations; they wrote: "The common seasonal flu vaccinations seem relatively safe in patients who … still have active CIDP." Id.

Kuitwaard carries relatively little persuasive value. A key part of this article reports about the experience of 24 people, which is a relatively small number. See Radford v. Sec'y of Health & Hum. Servs., No. 18-704V, 2023 WL 2159306, at *9 (Fed. Cl. Spec. Mstr. Feb. 22, 2023). In essence, Kuitwaard is an article that collects numerous case reports into a series.

An example of an article containing a single case report was written by J.M. Brostoff and others. These authors reported that a 74-year-old man received a flu vaccination and two days later, developed neurologic problems, which were eventually diagnosed as CIDP. Exhibit 44 at 229 (Brostoff). In the authors' discussion, they wrote:

> Viruses and viral vaccines have been proposed as putative triggers in the pathogenesis of autoimmune disease [2] with postulated mechanisms including antigen mimicry, triggering self-reactive T-cell clones, and cytokine upregulation that may induce aberrant MHC class II expression. Whilst autoimmune neurological sequelae of influenza vaccination have been described, the development of CIDP after influenza vaccination has not been previously reported.

Id.[10] They also postulated: "The patient's progressive deterioration soon after vaccination suggests that this case of CIDP was triggered by vaccination." Id.

The Institute of Medicine (now known as the National Academy of Medicine) considered the Brostoff case report but found that it "did not contribute to the weight of mechanistic evidence." Exhibit A, tab 4 at 335 (Stratton). This article did not contain information consistent with causation beyond temporality and the temporal relationship may have been too short. Id.

In the context of litigation, case reports often do not receive much consideration as evidence of causation. In general, case reports provide little, if any, information helpful to determining causation because they present only a temporal sequence of events in which the vaccination preceded an adverse health event. See K.O. v. Sec'y of Health & Hum. Servs., No. 13-472V, 2016 WL 7634491, at *11-12 (Fed. Cl. Spec. Mstr. July 7, 2016) (discussing appellate precedent on case reports). In accord with these authorities, the undersigned declines to afford the Kuitwaard case series or the Brostoff case report much weight in determining whether the flu vaccine can cause CIDP.

The foregoing analysis addresses the articles about CIDP that the parties put forward in their briefs. To a large extent, these articles constitute the main direct evidence regarding flu vaccine causing CIDP. These are the articles on which Dr. Nadareishvili has based his opinion. See Exhibit 30 at 7-16 (discussing general causation).

Beyond these articles, Dr. Nadareishvili does not add much on CIDP. He spends a great deal of attention on GBS, which is discussed below. With respect to CIDP, he states "that autoimmunity in CIDP is most likely mediated by antibodies directed against myelin antigens, along with autoreactive T cells and macrophages that invade the myelin sheath, axonal membranes, and/or the nodes of Ranvier." Exhibit 30 at 11. The actual source of this statement is Dalakas. Exhibit 62 at 1. This statement reveals the lack of knowledge about CIDP as Dr. Nadareishvili identifies three components of the immune system (antibodies, autoreactive T cells, and macrophages) that might attack three components of the nervous system (the myelin sheath, axonal membranes, and the nodes of Ranvier). The lack of

[10] The reference to "mimicry" makes this the third article discussing molecular mimicry in the context of CIDP.

information is shown more vividly in the Dalakas article: "no specific antibody has yet been identified as the causative factor in CIDP, in spite of the compelling indirect evidence." Exhibit 62 at 662 (Dalakas). Dalakas also points out that unlike GBS, "there is no convincing evidence that viral infections are antecedent events in CIDP." Id.

At the end of the day, there is not sufficient evidence to support a finding that molecular mimicry is a persuasive theory to explain how flu vaccines might cause CIDP. The basic problem, as Dr. Wilson explains, is that "No one knows what triggers CIDP." Exhibit C at 2. As Dalakas states, the medical community does not know the antigen that could be the target for an autoimmune attack. Exhibit 62 at 662. For a complex list of potential targets, see Exhibit 32 at 769 (Lunn and Sheikh). Without having some well-informed ideas of the target antigen and how an attack on the antigen leads to CIDP, it is difficult to accept, on a more likely than not basis, the proposition that the flu vaccine contributes to a poorly understand process.

The lack of definitiveness in Dr. Nadareishvili's reports makes his reports comparable to the reports in Dennington, which were found insufficient to explain how Tdap vaccine might cause GBS. Dennington and earlier cases such as W.C., Caves, and Yalacki contradict Mr. Hoffman's contention that: "To demand direct evidence in medical literature explaining precisely how influenza vaccine causes CIDP, and identification of the specific antibody triggered and the neurologic structure that is the targeted antigen would elevate Petitioner's burden contrary to the law." Pet'r's Reply at 6. As discussed in section IV.A. above, Mr. Hoffman attempts to lower his burden of proof.

Although the difference in perspective regarding the burden of proof appears to be the main point of departure between Dennington and Mr. Hoffman's case, the evidence differs as well. The main contrast might be Dr. Nadareishvili's attempted analogy between GBS and CIDP. That point is taken up next.

b) Flu infections, flu vaccines, and GBS

Mr. Hoffman heavily relies upon an analogy between Guillain-Barré syndrome and chronic inflammatory demyelinating polyneuropathy. In his view, because Guillain-Barré syndrome is a demyelinating disorder of the peripheral nervous system that has been linked to the flu vaccine, it is reasonable to infer that chronic inflammatory demyelinating polyneuropathy, which is also a demyelinating disorder of the peripheral nervous system, is linked to the flu

vaccine. Pet'r's Br. at 19-24; Pet'r's Reply at 6-8. Contrastingly, the Secretary argues that this analogy is inapt because Guillain-Barré syndrome differs from chronic inflammatory demyelinating polyneuropathy. Resp't's Br. at 9-10.

Mr. Hoffman's attempted method of proof is legitimate. Petitioners may try to establish their cases through circumstantial evidence. Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1324 (Fed. Cir. 2006). Whether the reasoning is persuasive depends upon several factual propositions.

GBS is both similar to and different from CIDP. One simple point of similarity is that both conditions are believed to involve an attack on the myelin in peripheral nerves. One simple point of contrast is that GBS is a monophasic disease and CIDP is a chronic disease. For purposes of determining whether a flu vaccine can cause CIDP, which is actually a question Mr. Hoffman's claim raises, a key point regarding the analogy between GBS and CIDP is what is known about the etiology of the two conditions.

The etiology of GBS is coming into focus. Detailed experiments with animal models have demonstrated that molecular mimicry between an infectious organism, C. jejuni, and portions of peripheral nerves, known as gangliosides, can cause GBS. Exhibit 49 (Yuki). Infections with C. jejuni, which cause gastrointestinal distress, have preceded cases of GBS in humans. Winkler v. Sec'y of Health & Hum. Servs., No. 18-203V, 2021 WL 6276203, at *2 (Fed. Cl. Spec. Mstr. Dec. 10, 2021), mot. for rev. denied, 2022 WL 1528779 (Fed. Cl. May 13, 2022), aff'd, Fed. Cir. Dec. 13, 2023. Thus, review articles have reported molecular mimicry as a mechanism by which GBS can develop. See, e.g., Exhibit 32 at 759 (certain subtypes of GBS "provide some of the best available evidence to support the hypothesis of molecular mimicry as a pathogenic mechanism underlying post-infections autoimmune disorders") (Lunn and Sheikh); Exhibit 39 at 286 (Yan); Exhibit 42 at 371 (Sheikh); Exhibit 61 at 2607 (Willison and Yuki).

Furthermore, some epidemiologic studies, particularly involving the 2009 H1N1 flu vaccine, have discovered a slight increase in the incidence of GBS among people receiving a flu vaccine. 80 Fed. Reg. 45132, 45145-46 (July 29, 2015). But, according to the Secretary, "there is no evidence demonstrating that current formulations of the seasonal influenza vaccine can cause GBS." Id. at 45146. Overall, the Secretary found that the evidence and policy grounds supported a proposal to associate the flu vaccine with GBS on the Vaccine Injury Table. 80 Fed. Reg. 45132, 45145-46 (July 29, 2015). The Secretary eventually

adopted this proposed modification. 82 Fed. Reg. 6294 (Jan. 19, 2017).[11] The change to the Vaccine Injury Table was in accordance with activities at the Office of Special Masters. See Heinzelman v. Sec'y of Health & Hum. Servs., No. 07-01V, 2008 WL 5479123, at *5 (Fed. Cl. Spec. Mstr. Dec. 11, 2008) (finding that the Secretary did not contest the first Althen prong when a petitioner alleged a flu vaccine caused her GBS), mot. for rev. denied, 98 Fed. Cl. 808, 812-15 (2011) (addressing burden of proof for potential causative factors other than a vaccine), aff'd on unrelated point regarding damages, 681 F.3d 1374 (Fed. Cir. 2012); see also Woods v. Sec'y of Health & Hum. Servs., No. 10-377V, 2012 WL 4010485, at *7 (Fed. Cl. Spec. Mstr. Aug. 23, 2012) (noting that parties informally resolve most flu vaccine-GBS cases).

However, the data that allowed the Secretary to associate the flu vaccine with GBS is lacking for CIDP. There is neither the quality nor the quantity of evidence regarding any causes of CIDP. The contrast in knowledge about the causes of GBS and in knowledge about the causes of CIDP is reflected in multiple articles. See, e.g., Exhibit 32 at 758-67 (Lunn and Sheikh). A group assembled to form the Brighton Collaboration GBS Working Group maintained that CIDP "is thought to be clinically and pathologically distinct from GBS." Exhibit A, tab 3 at 602 (Sejvar).

Under these circumstances, the inference that Mr. Hoffman requests---a finding that the flu vaccine can cause CIDP because the flu vaccine can cause GBS---is at least one step too far to be persuasive. Although it seems likely that preponderant evidence shows that the flu vaccine can cause GBS, this evidence is not certain. See Exhibit 47 (Wang) (finding no link between flu vaccines and GBS antiganglioside antibodies). Of course, due to the Secretary's listing the flu vaccine and GBS on the Vaccine Injury Table, the parties no longer litigate whether the flu vaccine can cause GBS. The point is not to suggest that the Secretary somehow reached the wrong conclusion. The point is that one of Mr. Hoffman's postulates, that the flu vaccine can cause GBS, is someplace above tentative but someplace below established. Any attempt to extend the proposition that the flu vaccine can cause GBS should acknowledge that the starting point has

[11] While the Secretary delayed implementing this rule, 82 Fed. Reg. 11321 (Feb. 22, 2017), the Vaccine Injury Table has been changed.

some questions. The analogy between GBS and CIDP also falters because the evidence about the causes of GBS have not been found as causes for CIDP.

Accordingly, Mr. Hoffman's proposed comparison to GBS does not carry such persuasive value that this evidence overcomes the shortfalls regarding the evidence about CIDP specifically. See section IV.B.2.a) above; see also Howard, 2023 WL 4117370, at *6 (finding that special master was not arbitrary in declining to extend research on GBS to CIDP). Accordingly, Mr. Hoffman has failed to meet his burden of proof regarding Althen prong one.

C. Other Cases from the Vaccine Program

The foregoing analysis is based upon the evidence and the parties' arguments about the evidence. See 42 U.S.C. § 300aa–13(a)(1) (directing a special master to consider "the record as a whole"). Another point meriting consideration is how other judicial officers have addressed similar points, even though those resolutions are not binding. Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1358-59 (Fed. Cir. 2019). Decisions from special masters do not bind other special masters because, in part, different special masters can weigh even similar evidentiary records differently. Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357, 1368 (Fed. Cir. 2000).

The parties were encouraged to identify relevant cases involving a reasoned outcome. Order for Briefs, issued July 18, 2022, at 6. The parties cited Mason v. Sec'y of Health & Hum. Servs., No. 17-1383V, 2022 WL 600415 (Fed. Cl. Spec. Mstr. Feb. 4, 2022), and Jacunski v. Sec'y of Health & Hum. Servs., No. 09-524V, 2014 WL 5168422 (Fed. Cl. Spec. Mstr. Sep. 23, 2014). Resp't's Br. at 13-14, 19; Pet'r's Reply at 15 (arguing that Jacunski reached an incorrect conclusion regarding the IOM report).

In Jacunski, the petitioner's expert relied on "molecular mimicry" to support that the vaccines significantly aggravated the petitioner's CIDP, suggesting that "an antigen within the influenza vaccine erroneously prompted [p]etitioner's immune system to attack her own issues, thereby exacerbating her CIDP." Jacunksi, 2014 WL 5168422, at *12. The special master found that there was no merit in the petitioner's expert's theory:

> But, Dr. Morgan failed to offer any *evidence* or even any *explanation* to support this vague suggestion. In his expert report and his testimony, Dr. Morgan introduced

> the concept of an antigen that is part of the influenza vaccine, which may have caused a harmful response. However, when pressed for more details, he had no idea what particular antigen within the vaccine might have caused the alleged molecular mimicry effect. Indeed, he acknowledged that he knows of no evidence to support the idea that a flu vaccine can cause CIDP via molecular mimicry -- "it's a theory" was the best he could offer.

Id. (citations omitted).

In a more recent case, John Mason alleged that a flu vaccine caused him to suffer CIDP. Mason, 2022 WL 600415, at *1. He relied upon reports from a neurologist, Lawrence Steinman, who has often assisted people claiming that a vaccine injured them. Dr. Steinman proposed molecular mimicry with an attack on myelin basic protein and other components of the nervous system. Id. at *4-8. The chief special master denied the claim because Mr. Mason suffered from CIDP before he received the vaccination, a sequence of events precluding a finding of causation. Id. at *1, 23-26. Although unnecessary to the outcome, the chief special master also evaluated the first Althen prong, whether a flu vaccine can cause GBS. The chief special master stated: "I have identified no more-recent *reasoned* decisions in which a special master explained how or why the flu vaccine was likely causal of the claimant's CIDP." Id. at *22. Although the chief special master recognized that some special masters have found that flu vaccine can cause CIDP, the basis for those findings was questionable as

> special masters have consistently relied on the fact that CIDP and GBS have tended to be lumped together as comparable peripheral neuropathies—leading them to assume that the extensive science supporting causation for GBS after vaccination applies to CIDP, but without close consideration of the actual persuasiveness of a claimant's prong one showing, based on expert opinions or relevant literature specific to CIDP.

Id.

The chief special master eventually concluded that "despite my reasoned doubts, the record as developed in this case preponderates—if barely— in Petitioner's favor" on Althen prong one. Id. at *26. The chief special master

recounted the differences between GBS and CIDP, demonstrating that a comparison was not appropriate. "However, two considerations [led] [the chief special master] to determine that (regardless of these misgivings) the first Althen prong was in this case preponderantly established---if only by inches." Id. at *27. Those factors were: first, the presence of "some reliable literature (specifically Kira and Devaux)" and second, the "prior Program findings on the issue of flu vaccine being causal of CIDP." Id. The chief special master recognized that that the outcome on prong one might have differed if the Secretary had "attempt[ed] to rebut Dr. Steinman's points on causation." Id. at *27 n.21.

Mason differs from Mr. Hoffman's case in multiple respects. First, unlike Dr. Nadareishvili, Dr. Steinman arguably identified points of homology. Second, the Kira and Devaux articles that the chief special master highlighted in Mason are not part of the record in Mr. Hoffman's case. Third, in Mr. Hoffman's case, the Secretary has presented the opinion of Dr. Wilson, who opined that "there is a dearth of data . . . that suggest an increased risk for CIDP in influenza-vaccinated persons." Exhibit A at 5. Accordingly, if it is taken for granted that the evidence in Mason crossed the evidentiary standard "by inches," it is easy to conclude that the evidence in Mr. Hoffman's case falls short. None of the factors that were critical to the chief special master's assessment in Mason are present in Mr. Hoffman's case.

D. Synopsis regarding Prong One

To meet his burden regarding Althen prong one, Mr. Hoffman has presented the theory of molecular mimicry. This theory is not fanciful. It may very well be the case that molecular mimicry is a biologically plausible theory to explain how the flu vaccine might cause GBS.

However, as explained in section IV.A, "biologic plausibility" is not the evidentiary standard. Under the correct evidentiary standard, Mr. Hoffman's evidence fails to measure up. There is little reliable support for claiming that the flu vaccine can cause CIDP, in part, because there is little understanding about any cause of CIDP.

V. Comments on Remaining *Althen* Prongs

When petitioners fail to establish one Althen prong, additional analysis is not required. Mr. Hoffman's case is resolved solely on the basis of Althen prong one.

If Mr. Hoffman had succeeded on Althen prong one, then it is likely that he would have prevailed on Althen prong three, which concerns timing. See Exhibit A at 5. Persuasive proof on timing is not dispositive because "[t]emporal association is not sufficient, however, to establish causation in fact." Grant v. Sec'y of Health & Hum. Servs., 956 F.2d 1144 (Fed. Cir. 1992).

Finally, any analysis of Althen prong two is complicated for at least two reasons. First, to the extent that Mr. Hoffman's molecular mimicry theory is premised on the idea that there is homology between a flu vaccine and gangliosides, this theory appears not to explain how Mr. Hoffman's CIDP developed because he tested negative for anti-ganglioside antibodies. Exhibit 9 at 32; see also Resp't's Br. at 11.

Second, Dr. Wilson stated that Mr. Hoffman's pre-existing CLL is "associated with an increased risk of CIDP." Exhibit A at 5. The evidentiary value of this statement appears unclear as Dr. Wilson's supplemental report clarifies that he "intentionally did not use the words 'cause' or 'causal' when discussing the *association* between hematologic malignancies and CIDP." Exhibit C at 2. An in-depth evaluation is not required to resolve Mr. Hoffman's case.

VI. Conclusion

Mr. Hoffman merits sympathy for suffering a chronic condition. But he has not presented persuasive evidence that a flu vaccine was the cause of his CIDP. Therefore, Mr. Hoffman is not entitled to compensation.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, which are available on the website for the Court of Federal Claims.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master

Appendix: Medical Literature Cited[12]
(listed alphabetically by lead author's last name)

1. C. Bouchard et al., Clinicopathologic findings and prognosis of chronic inflammatory demyelinating polyneuropathy, 52 NEUROLOGY 498 (1999), filed as Exhibit 56.

2. J.M. Brostoff et al., Post-influenza vaccine chronic inflammatory demyelinating polyneuropathy, 37 AGE AND AGEING 229 (2008), filed as Exhibit 44.

3. Marinos Dalakas, Pathogenesis of immune-mediated neuropathies, 1852 BIOCHIM BIOPHYS ACTA 658 (2014), filed as Exhibit 62.

4. Robert Fujinami et al., Molecular Mimicry, Bystander Activation, or Viral Persistence: Infections and Autoimmune Disease, 19 CLIN MICROBIOL REV 80 (2006), filed as Exhibit 35.

5. Angelika Hahn et al., Chronic Inflammatory Demyelinating Polyradiculoneuropathy, 99 NEUROLOGY 2221 (2005), filed as Exhibit 51.

6. Krista Kuitwaard et al., Recurrences, vaccinations and long-term symptoms in GBS and CIDP, 14 JOURNAL OF THE PERIPHERAL NERVOUS SYSTEM 310 (2009), filed as Exhibit 60.

7. Michael Lunn & Kazim Sheikh, Peripheral Neuropathies, 5 THE AUTOIMMUNE DISEASES 757 (2014); filed as Exhibit 32.[13]

8. Emily Mathey et al., Chronic inflammatory demyelinating polyradiculoneuropathy: from pathology to phenotype, 86 J NEUROL NEUROSURG PSYCHIATRY 973 (2015), filed as Exhibit 50.

---

[12] Although this appendix provides bibliographic information for all articles cited in the decision, all articles have been reviewed.

[13] "Exhibit 31" is shown on the actual medical article; however, the comprehensive exhibit list, submitted on April 1, 2023, indicates that this article is "Exhibit 32." "Exhibit 31" is shown on Dr. Nadareishvili's curriculum vitae as well. The comprehensive exhibit list indicates that Dr. Nadareishvili's curriculum vitae is "Exhibit 31." It appears that the Exhibit number on the medical article is inaccurate. This decision will cite to this medical article as Exhibit 32.

9. P.A. McCombe et al., Chronic Inflammatory Demyelinating Polyradiculoneuropathy: A Clinical And Electrophysiological Study of 92 Cases, 110 BRAIN 1617 (1987), filed as Exhibit 55.

10. James Sejvar et al., Guillain-Barre syndrome and Fisher syndrome: Case definitions and guidelines for collection, analysis, and presentation of immunization safety data, 29 VACCINE 599 (2011), filed as Exhibit A, tab 3.

11. K.A. Sheikh et al., *Campylobacter jejuni* lipopolysaccharides in Guillain-Barre syndrome: Molecular mimicry and host susceptibility, 51 NEUROLOGY 371 (1998), filed as Exhibit 42.

12. Kathleen Stratton et al., Influenza Vaccine, ADVERSE EFFECTS OF VACCINES: EVIDENCE AND CAUSALITY 293 (2012), filed as Exhibit A, tab 4.

13. David Wang et al., No evidence of a link between influenza vaccines and Guillain-Barre syndrome – associated antiganglioside antibodies, 6 INFLUENZA OTHER RESPIR VIRUSES 159 (2011), filed as Exhibit 47.

14. M.D. Weiss et al., Molecular mimicry in chronic inflammatory demyelinating polyneuropathy and melanoma, 51 NEUROLOGY 1738 (1998), filed as Exhibit 41.

15. Hugh Willison & Nobuhiro Yuki, Peripheral neuropathies and anti-glycolipid antibodies, 125 BRAIN 2591 (2002), filed as Exhibit 61.

16. Wei Xing Yan et al., P0 Protein Is a Target Antigen in Chronic Inflammatory Demyelinating Polyradiculoneuropathy, 50 ANN NEUROL 286 (2001), filed as Exhibit 39.

17. Nobuhiro Yuki et al., Carbohydrate mimicry between human ganglioside GM1 and *Campylobacter jejuni* lipooligosaccharide causes Guillain-Barre Syndrome, 101 PROC NATL ACAD SCI 11404 (2004), filed as Exhibit 49.